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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,088

03/22/2004

Mary R. Flack

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7590

05/01/2006

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,088

Applicant(s)

FLACK ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-20 and 22-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 10, 19 and 26 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6-9, 11-18, 20, 22-25 and 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-2-06; 3-10-06</u> | 6) <input type="checkbox"/> Other: _____ |

Claims 1-4, 6-20 and 22-37 are presented for examination.

Applicants' amendment filed February 2, 2006; and the information disclosure statements filed February 2, 2006 and March 10, 2006 have been received and entered.

Accordingly, the rejection made under 35 USC 102(b) as set forth in the previous Office action dated October 3, 2005 at pages 2-3 is hereby withdrawn since the applicants amended claim 1.

Reissue Applications

Allowable Subject Matter

Claims 3, 10, 19 and 26 are allowable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' specification does not disclose or describe the newly amended phrase " wherein said composition rotates the plane of polarized light in the (-)

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direction". Applicants' response stated on page 7, under Discussion of Claim Amendments Relative to Issued Claims, second paragraph, that the claim amendments are supported by the specification at, for example, column 7, lines 29-66. However, this citation does not describe the newly added subject matter.

Claims 8-14 and 16 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15, 17, 24 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznetsova et al., "Determination of the cytotoxic effect and antitumor activity of gossypol and some of its derivatives", Deposited Doc. (1979), VINITI 409-79, pp.7 (enclosed abstract).

Kuznetsova et al. show the inhibitory activity of gossypol and gossypolone against human pancreatic carcinoma. Clearly, the cited reference anticipates the applicants' instant invention, treat a cancer, especially pancreatic carcinoma; therefore, the instant invention is unpatentable.

Claims 1, 17, 24 and 36 are not allowed.

Claims 8, 9, 31-33, 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by V. Band et al., "Cytocidal Effects of Gossypol and Its Optical Isomers

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on Reproductive Cancer Cell Lines", Gynecologic Oncologists, (1986), 23(2), p. 261, (AH of PTO-1449).

V. Band et al. teach that (-) gossypol is more potent than (+) gossypol and may be clinically useful in the treatment of reproductive tract cancers, such as ovarian and testicular cancers. Clearly, the cited reference anticipates the applicants' instant invention, to treat ovarian or testicular cancer with the administration of (-) gossypol; therefore, the instant invention is unpatentable.

Claims 8, 9, 31-33, 35 and 37 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 6, 7, 18, 20, 22, 23, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuznetsova et al., "Determination of the cytotoxic effect and antitumor activity of gossypol and some of its derivatives", Deposited Doc. (1979), VINITI 409-79, pp.7 (enclosed abstract) in view of V. Band et al., "Cytocidal Effects of Gossypol and Its Optical Isomers on Reproductive Cancer Cell Lines", Gynecologic Oncologists, (1986), 23(2), p. 261, (AH of PTO-1449).

Kuznetsova et al. were discussed above supra for the use of gossypol and gossypolone as antitumor agents effective against human pancreatic carcinomas.

The instant invention differs from the reference in that the cited reference does not teach gossypol or gossypol are effective in the treatment of cancers disclosed in claims 2, 18 and 25. However, the secondary reference, V. Band et al., teaches the (-) isomer of gossypol is effective against reproductive tract cancers. Since gossypol contains both the (-) and (+) isomers together, obviously gossypol would possess the same activity to treat reproductive tract cancers in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach the blood concentration of said compound disclosed in claim 4. However, the determination of the blood concentration of the said compound having optimum effective against various cancers cells is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine an optimum blood concentration to get the maximum effectiveness of gossypolone.

The instant invention differs from the cited reference in that the cited reference does not teach the dosage range of said compound administered in various modes as disclosed in claims 6, 7, 20, 22, 23 and 27-30. However, the determination of the blood concentration of the said compound having optimum effective against various cancers cells is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine an optimum dosage to get the maximum effectiveness of gossypolone.

Claims 2, 4, 6, 7, 18, 20, 22, 23, 25 and 27-30 are not allowed.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Band et al., "Cytocidal Effects of Gossypol and Its Optical Isomers on Reproductive Cancer Cell Lines", Gynecologic Oncologists, (1986), 23(2), p. 261, (AH of PTO-1449).

V. Band et al. were discussed above supra for the use of (-) gossypol is effective against reproductive tract cancers.

The instant invention differs from the cited reference in that the cited reference does not teach the blood concentration of said compound disclosed in claim 11. However, the determination of the blood concentration of the said compound having optimum effective against various cancers cells is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine an optimum blood concentration to get the maximum effectiveness of (-) gossypol.

The instant invention differs from the cited reference in that the cited reference does not teach the dosage range of said compound administered in various

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modes as disclosed in claims 12-14. However, the determination of the blood concentration of the said compound having optimum effective against various cancers cells is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine an optimum dosage to get the maximum effectiveness of (-) gossypol.

Claims 11-14 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

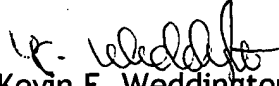
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
April 17, 2006